

**K220283 TENS & PMS (Model:SM9009, SM9021, SM9128H, SM9015, SM9055, SM9033)**May 2, 2022  
90 days to decisionK220283 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k220283/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Feb 1, 2022
Decision date	May 2, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hong Qiangxing (Shenzhen) Electronics Limited</b>
Location	Shanghai, CN
Contact	Xu Jianhua
510(k) history	9 submissions · 9 cleared · 2013-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai CV Technology Co., Ltd.</b>
Contact	Doris Dong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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